TIBCO Spotfire® Clinical 3.3

Installation and Configuration Manual

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Contents

1 Introduction 4

1.1 Prerequisites 4
1.2 Roles 4

2 Installing TIBCO Spotfire Clinical 5

2.1 Deploying SpotfireClinical.spk 5
2.2 Automation Services 6

3 Configuring the Information Model 9

3.1 Importing the Oracle Clinical Information Model 9
3.2 Modifying the Oracle Clinical Information Model 10

4 Configuring Access Rights 12

4.1 Assigning Folder Permissions 12
4.2 Assigning the License 13

5 Updating Clients with TIBCO Spotfire Clinical 14

6 Accessing TIBCO Spotfire Clinical 15

Appendix - Information Link and Data Source Setup 16

1 Introduction

TIBCO Spotfire Clinical allows end users to easily connect to Oracle® Clinical (OC) databases and open data from one or more clinical studies in TIBCO Spotfire. This document is used to help with installing and configuring the product for the end users.

1.1 Prerequisites

The instructions below assume that you have a working installation of TIBCO Spotfire 3.3.

You must also have access to a running TIBCO Spotfire Server, version 3.3, that TIBCO Spotfire will connect to. How to install a Spotfire Server is described in the "**TIBCO Spotfire Server - Installation and Configuration Manual**".

For more information on the system requirements of TIBCO Spotfire, see http://spotfire.tibco.com/sr.

There must be at least one Oracle Clinical instance available, with data from one or more studies.

1.2 Roles

Spotfire defines different roles for installing, configuring, and administering the different components of the system.

- **Spotfire Server Administrator**. This role is responsible for installing and configuring the Spotfire Server(s) and the Spotfire database. How to perform these tasks is described in the "**TIBCO Spotfire Server - Installation and Configuration Manual**".
- **Spotfire Admin**. This role is responsible for setting up users and groups in the Spotfire system, assigning licenses and preferences to the Spotfire groups, setting up the Spotfire Library, and deploying Spotfire software packages to the Spotfire Server. How to perform these tasks is described in the "**TIBCO Spotfire - Deployment and Administration Manual**".
- **Data Manager**. This role is responsible for setting up data sources and elements in Information Designer, so that the correct data becomes available for the end users.

These roles can be assigned to different persons or to the same person. It is important that the person or persons assuming the roles are familiar with each respective area of knowledge.

2 Installing TIBCO Spotfire Clinical

This chapter is intended for the **Spotfire Admin**.

Start by unzipping the downloaded TIBCO Spotfire Clinical package to a folder on your local disk (**TIB_spotclinical_3.3.0_win.zip**). The zip file includes this PDF document, release notes, the deployment files SpotfireClinical.spk (see below) and SpotfireClinical.Automation.spk, as well as the template information model OracleClinical.IM.part0.zip.

2.1 Deploying SpotfireClinical.spk

Use the Administration Console to deploy the SpotfireClinical.spk file as described below.

To deploy TIBCO Spotfire Clinical to the server:

1 Open the Administration Console located at `http://spotserver:port/spotfire/` (where spotserver is the name of one of your Spotfire servers and port is the port number, if other than the default) in a web browser.

2 Log in as a Spotfire Administrator.

3 Select the tab **Deployment**.

4 Select whether to deploy to the **Production Area** or to the **Test Area** from the View drop-down list at the top of the **Deployment** tab.

Comment: For more information about deployment areas and the distinction between them, see the TIBCO Spotfire - Deployment and Administration Manual.

5 Click the **Edit** button.

Response: The deployment tab will enter edit mode.

6 Click the **Add** button.

Response: The Add to Deployment dialog is displayed.

7 Click the **Browse** button.

Response: A File Upload dialog is displayed.

8 Browse to the **SpotfireClinical.spk** file and click **Open**.

9 Click **OK** in the **Add to Deployment** dialog to upload and add the file to the distribution.

Response: The list of packages is updated with the contents of the file.

10 Click the **Validate** button in the lower right corner to make sure the deployment is not damaged or corrupted in any way.

11 Click the **Save** button in the lower right corner to save and publish the deployment.

Response: The **Save Deployment** dialog is displayed.

12 Enter a version number and a description for the deployment and click the **OK** button.

For more information, see the online help of the Administration Console.

2.2 Automation Services

If you have access to TIBCO Spotfire Automation Services you must also deploy the SpotfireClinical.Automation.spk file to the Spotfire server. Use the Administration Console to deploy the file as described below.

When all steps below have been performed, it will be possible to add a Replace Oracle Clinical Data job in the Automation Services Job Builder.

Note: SpotfireClinical.Automation.spk should only be deployed when using TIBCO Spotfire Clinical together with TIBCO Spotfire Automation Services. Deploying this package on a server without Automation Services will result in an error.

2.2.1 Deploying the Automation Services Package

▸ To deploy TIBCO Spotfire Clinical for Automation Services to the server:

1 Open the Administration Console located at `http://spotserver:port/spotfire/` (where spotserver is the name of one of your Spotfire servers and port is the port number, if other than the default) in a web browser.

2 Log in as a Spotfire Administrator.

3 Select the tab **Deployment**.

4 Select whether to deploy to the **Production Area** or to the **Test Area** from the View drop-down list at the top of the **Deployment** tab.

Comment: For more information about deployment areas and the distinction between them, see the TIBCO Spotfire - Deployment and Administration Manual.

5 Click the **Edit** button.

Response: The deployment tab will enter edit mode.

6 Click the **Add** button.

Response: The Add to Deployment dialog is displayed.

7 Click the **Browse** button.

Response: A File Upload dialog is displayed.

8 Browse to the **SpotfireClinical.Automation.spk** file and click **Open**.

9 Click **OK** in the **Add to Deployment** dialog to upload and add the file to the distribution.

Response: The list of packages is updated with the contents of the file.

10 Click the **Validate** button in the lower right corner to make sure the deployment is not damaged or corrupted in any way.

11 Click the **Save** button in the lower right corner to save and publish the deployment.

Response: The **Save Deployment** dialog is displayed.

12 Enter a version number and a description for the deployment and click the **OK** button.

For more information, see the online help of the Administration Console.

2.2.2 Updating Automation Services

Two DLL files need to be copied to your Automation Services installation: Spotfire.Dxp.OracleClinical.Automation.dll and Spotfire.Dxp.OracleClinical.dll.

▸ To copy the DLL files:

1 Locate the **AutomationServices folder** of the downloaded and unzipped TIBCO Spotfire Clinical package.

2 Copy **Spotfire.Dxp.OracleClinical.Automation.dll** and **Spotfire.Dxp.OracleClinical.dll** to the **bin** folder of your Automation Services installation on your server, e.g., C:\Program Files (x86)\TIBCO\Automation Services\3.3\webroot\bin

You also need to add a line of text to the AddIns.xml file on the server where Automation Services is installed.

▸ To edit the AddIns.xml file:

1 On the Automation Services server, locate the **bin** folder, e.g., C:\Program Files (x86)\TIBCO\Automation Services\3.3\webroot\bin

2 Open the file **AddIns.xml** in a text editor and add the following line to the <AddIn Registry> section:

```
<AddIn
FullTypeName="Spotfire.Dxp.OracleClinical.Automation.OracleClinicalTa
sksAddIn, Spotfire.Dxp.OracleClinical.Automation" />
```

When finished your AddIns.xml file should look something like this:

```
<?xml version="1.0" encoding="utf-8" ?>

<!--

    This is the AddIns.xml file which must be deployed together with
the AS assembly in the Automation Services directory.

  -->

<AddInRegistry xmlns="http://www.spotfire.com/schemas/
AddInRegistry1.0.xsd" SchemaVersion="1.0">

<!--  namespace, assembly   -->

  <AddIn FullTypeName="Spotfire.Dxp.Automation.Framework.
FrameworkAddIn, Spotfire.Dxp.Automation.Framework" />

  <AddIn FullTypeName="Spotfire.Dxp.Automation.Tasks.BaseTasksAddIn,
Spotfire.Dxp.Automation.Tasks" />

  <AddIn FullTypeName="Spotfire.Dxp.OracleClinical.Automation.
OracleClinicalTasksAddIn, Spotfire.Dxp.OracleClinical.Automation" />

 </AddInRegistry>
```

3 Configuring the Information Model

This chapter is intended for the **Data Manager**.

Access to Oracle Clinical metadata and individual trial views is provided through a generic Information Model (IM) that is shipped as part of TIBCO Spotfire Clinical. Import the information model and edit the data source by adding information relevant to your Oracle Clinical database in Information Designer, as described below.

3.1 Importing the Oracle Clinical Information Model

1 Place the **OracleClinical.IM.part0.zip** file in the Shared Disk Location on the TIBCO Spotfire Server.

Comment: See the **TIBCO Spotfire - Installation and Configuration Manual** for more information about the Shared Disk Location.

2 Log into TIBCO Spotfire as a user with Library Administration rights.

3 Select **Tools > Library Administration**.

Response: The Library Administration tool is displayed.

4 Click on the **Import** button.

Response: The Import dialog is displayed.

5 Click **Browse** and select the **OracleClinical.IM.part0.zip** file.

6 Click **OK**.

7 Select whether or not to **Include permissions**. If you do not include any permissions, the imported content will inherit the permissions of the destination folder.

Comment: In most cases, you will probably need to modify the permissions after the import is done, to fit your current user structure.

8 Select **Automatically assign new name or GUID to imported item** to generate new identifiers for potential name and/or GUID conflicts, and click **OK**.

Comment: This is especially important if multiple Oracle Clinical information models are being used, since you will overwrite a previously added Oracle Clinical information model if conflicts are left unhandled.

Response: The Select Destination Folder dialog is displayed.

9 Browse to the folder where you wish to import the Oracle Clinical information model, or create a new folder, then click **OK**.

Comment: Typically this folder would have the same name as the Oracle Clinical database this information model should be connected to.

Comment: Access to individual data sources are handled by the regular Library access control, so make sure that the folder permissions for the selected folder is sufficient for the intended end users.

10 Click **Close** when the status messages states “Import done”.

Comment: You can click **Refresh** to update the status messages in the dialog, or just wait until all messages are shown and the import is finished.

11 If you use more than one Oracle Clinical database, you need to repeat steps 4-10 and import the information model once for each instance.

Comment: You can also make a copy of the imported information model template and make the modifications described below on each copy.

3.2 Modifying the Oracle Clinical Information Model

1 Select **Tools > Information Designer**.

Response: The Information Designer is displayed.

2 In the Data Sources pane, right-click on the newly imported data source, named Oracle Clinical Data Source Template, and select **Edit...**.

Comment: Note that you **must not** change the Open session commands supplied with the template - these commands are required by Oracle Clinical to set up the connection, see also the Data Source section on page 13.

3 Change the **Name** of the data source, e.g., to the name of your Oracle Clinical database.

Comment: This name will be shown to the end users when adding Oracle Clinical data to an analysis and it is used to distinguish between multiple instances of Oracle Clinical data sources.

4 Provide a **Connection URL**, a **Username** and a **Password** to your Oracle Clinical database.

Comment: This is required in order to save the data source, even if you intend to apply user authentication on the data source.

5 If desired, change the **User authentication** setting for the data source.

Comment: The Oracle Clinical data source template is distributed with user authentication turned on, but this can be changed if necessary.

6 If desired, modify the **Credentials timeout** setting.

Comment: Credentials are always cached for the remainder of a client session, but the server-side cache settings can be modified. In the Oracle Clinical Data Source Template, the default server-side credentials caching has been set to 0.25 hours. This means that if a user authenticates against an Oracle Clinical instance and then restarts the client within 15 minutes, he/she will not be re-prompted for Oracle Clinical credentials. If he/she waits more than 15 minutes before restarting the client, he/she will be required to authenticate again. Increase or decrease the number to specify how long the server should save the user credentials before requiring another login to the data source. See the Data Source Tab topic in the online help of TIBCO Spotfire for more information about the Credentials timeout setting.

7 **Save** the data source.

8 If you use more than one Oracle Clinical instance, you need to repeat steps 2-7 and modify the data source created for each instance.

4 Configuring Access Rights

The access to clinical data in TIBCO Spotfire is controlled by two different things, in addition to the data source authentication:

- The folder permissions to the Oracle Clinical information model.
- The licenses enabled for each end user.

It is very important to protect the imported Oracle Clinical information model so that it cannot be changed or tampered with by unauthorized users.

4.1 Assigning Folder Permissions

This chapter is intended for the **Data Manager**.

1 Log into TIBCO Spotfire as a user that has Spotfire Administration or Library Administration rights.

2 Select **Tools > Library Administration**.

3 Select the folder containing the Oracle Clinical information model you want to assign access rights to and click on the **Edit...** link next to the **Permissions for Selected Folder** header.

4 Assign “Access” permission for those users/groups that should be consumers of reports containing data from this folder.

5 Assign “Browse + Access (+ Modify)” permission to those users (Data Managers) or groups (containing Data Managers) that should be able to use the information links when creating analysis files.

Comment: Data Mangers responsible for setup and use of the information model and its containing entities when creating reports should be given a minimum of Browse and Access rights. If Data Managers should have the possibility to edit a specific Information Model, the permission should be set to Browse, Access and Modify.

6 Full Control should only be given to those users who need to administrate the access to a particular Information Model, e.g., assign the access rights to new Data Managers or revoke access rights of people who should no longer be part of a particular clinical trial.

7 When you are done, click **OK** to close the Folder Permissions dialog.

8 Make sure that steps 3-7 are performed for all added information models, then click **Close**.

4.2 Assigning the License

This chapter is intended for the **Spotfire Admin**.

The Open Oracle Clinical Data function gives access to the Add Oracle Clinical Data wizard, which gives easy access to Oracle Clinical data through the Add Data Tables tool, as well as the Replace Oracle Clinical Data wizard. No users or groups will have this license enabled upon installation. It must be enabled by following the steps below.

Note: Only those users who will create reports need to have the TIBCO Spotfire Clinical license enabled. Consumers of reports based on clinical data do not need a specific license.

To assign the licence:

1 Log into TIBCO Spotfire as a user with Administration privileges.

2 Select **Tools > Administration Manager**.

3 Go to the **Groups and Licenses** tab and select the group for which to enable the TIBCO Spotfire Clinical license.

Comment: Licenses are always assigned to groups, never to individual users.

4 On the **Licenses** tab, click **Edit**.

5 Assign the license by selecting the check boxes for the **TIBCO Spotfire Clinical** license group, and for the underlying **Open Oracle Clinical Data** function.

6 Repeat steps 3-5 for all groups that should have access to the Add Oracle Clinical Data functionality.

5 Updating Clients with TIBCO Spotfire Clinical

When the .spk file has been deployed to the Spotfire Server, you must perform some additional steps to update the Spotfire clients. Note that these steps must be performed on all computers running Spotfire.

To update the Spotfire Client:

1 Exit TIBCO Spotfire.

2 Restart TIBCO Spotfire and log in as usual. You will be notified that there are new packages deployed on the server. Accept the updates to download and install the new packages.

6 Accessing TIBCO Spotfire Clinical

First access to the clinical data is supplied through **File > Add Data Tables**. In the Add Data Tables dialog you can select one or multiple data tables to be added in a single step. For end users with access to the Open Oracle Clinical Data function, the Oracle Clinical Data... option will show up in the Add drop-down list in the Add Data Tables dialog.

See the **TIBCO Spotfire - User's Manual** or the online help for more information about Add Data Tables.

Replace a previously added Oracle Clinical study by selecting **File > Replace Oracle Clinical Data...**.

There is no need for any deployment on the TIBCO Spotfire Web Player server. Users of the Web Player will be able to connect to the clinical data directly, once the analysis has been set up. With TIBCO Spotfire Automation Services you can include the task "Set Data Source Credentials" in any automated job where data source authentication is required.

Appendix - Information Link and Data Source Setup

For every Oracle Clinical database, two information links are set up. These information links contain the queries used for finding studies and views, respectively, and the results are used to populate the Add Oracle Clinical Data user interface. The Add Oracle Clinical Data wizard will find the database by doing a search in the library for information links with the **OracleClinical.QueryType** property set. That way, library permissions can control which users and groups see which databases.

Information Links

The information links are set up using the following specification:

1. One information link is used for extracting the list of studies each end user has access to. It should include two columns:

/RXC/STUDY_ACCESS_ACCOUNTS/STUDY_ACCESS_ACCT_NAME

/RXC/USER_STUDIES/STUDY (not retrieved)

Two inner joins are needed:

/RXC/STUDY_ACCESS_ACCOUNTS/CLINICAL_STUDY_ID = /RXC_DES/CLINICAL_STUDIES/CLINICAL_STUDY_ID

/RXC/USER_STUDIES/STUDY = /RXC_DES/CLINICAL_STUDIES/STUDY

The property OracleClinical.QueryType should be set to “STUDIES”.

2. One information link is used for extracting the list of views in a study. It should have two columns:

/SYS/ALL_VIEWS/OWNER (not retrieved) with a single value prompt.

/SYS/ALL_VIEWS/VIEW_NAME (retrieved) with a filter:

%1 NOT IN ('RDCMS_VIEW', 'RESPONSES_VIEW')

The property OracleClinical.QueryType should be set to “VIEWS”.

Data Source

The data source must be configured with the following open session commands:

ALTER SESSION SET NLS_NUMERIC_CHARACTERS = '. ';

The information model distributed with TIBCO Spotfire Clinical includes the required elements, pointing to a generic data source. When making the modifications described in section 3.2 above, you should automatically end up with a working set of elements and information links.

Note that the data source template assumes that you have access to the Oracle native driver. If this should not be the case, you can modify the Type of the data source to use DataDirect instead.

To use the Oracle (DataDirect) driver instead of the Oracle native driver:

1 Right-click on the data source you want to change and select **Edit...** from the pop-up menu.

2 Change the data source **Type** from Oracle to **Oracle (Data Direct)**.

3 Edit the **Connection URL**.

4 Make sure the Open session command is set to ALTER SESSION SET NLS_NUMERIC_CHARACTERS = '. ';

5 **Save** the data source.

Changing the Available Views

The information model distributed with TIBCO Spotfire Clinical is set up to filter out some views from the list of available views, since they are normally of no interest to an end user.

To add more views to be filtered out (or to remove a filter), use the Information Designer and modify the VIEWS information link or the VIEW_NAME column element.

Note that modifications can only be done on a per Oracle Clinical database connection level, i.e., the same filter condition will apply to all users of this particular data source. Modifications cannot be customized on a per user/group level. If that type of behavior is desirable then you need to import, set up and configure another generic Oracle Clinical information model to point to the same Oracle Clinical database but with a modified filter condition. See “Modifying the Oracle Clinical Information Model” on page 10.